

Attorney Docket No.: 188-88 (S-10-US)**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**Applicant: **Masahiro Sasaki, et al.**

Group Art Unit: 1642

Serial No: **09/936,045**

Examiner: Yu, Misook

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Date: March 22, 2005

For: **FUNCTIONAL ORAL PREPARATIONS**

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION**I, Masahiro Sasaki, do hereby declare:**

1. I am one of the joint inventors of the invention being claimed in the above-identified patent application and fluent in the Japanese language;
2. I have read and understand the Office Action mailed October 27, 2004 by the Patent and Trademark Office in the above-identified application and the art being applied therein, namely Japanese Pat. No. 1-256351 to Hirabayashi Kiyoshi and U.S. Pat. No. 6,165,982 to Yamada et al. (hereinafter referred to as "JP 1-256351" and "Yamada et al.");
3. The present invention, provides an improved preparation for preventing colon cancer (and providing other gastrointestinal benefits) by administering an effective amount of water-soluble sericin or hydrolyzed product thereof. These benefits

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provided by the claimed invention have been explicitly documented in the demonstrative and comparative testing set forth in Test Examples 1-7 on pages 9-20 of the present application and illustrated, e.g., in accompanying Figs. 1-4;

4. In particular, the inventive functional oral preparation contains sericin which has been extracted as a single protein from silk worm cocoons or raw silk with a purity of 90% or higher (page 6, lines 1-43 of the present application), or hydrolyzed product having an average molecular weight range of at least 20,000, in an effective amount to prevent colon cancer in dosage form;

5. I have read and understand JP 1-256351 which fails to suggest to me, one skilled in the art, the chemical or physical structure of the sericin used in the claimed oral preparation for the following reasons;

6. The following is an English translation of an excerpt from the preparation part of the Examples in JP 1-256351:

"Example 1

Waste silkworm cocoons were subjected to a treatment in a solution of sodium carbonate of 0.5% at a bath ratio of 50 times and a bath temperature of 90 °C for 30 minutes twice. Then, the fibroin containing product was dissolved in an aqueous solution of calcium chloride and ethanol, thereafter suction-filtered and poured into a cellulose tube to dialyze to obtain an aqueous fibroin solution having a concentration of 4%. Then, both aqueous solutions were mixed in equal amounts to obtain an aqueous mixture solution which was added into commercially available 100% orange juice and then the pH was adjusted to 4 by using citric acid to obtain a food in which fibroin and sericin were gelled."

In the other Examples, the preparation of the silk proteins is not shown at all and the same silk protein prepared in Example 1 is used;

7. The above preparation conditions (i.e., 0.5% Na₂CO₃, 90 °C, 30 minutes x2) provide a sericin having an average molecular weight of only about 3,000;

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8. Furthermore, while the sericin used in JP1-256351 might be "water-soluble" just after being derived from silkworm cocoons or raw silk, nevertheless it is essential to JP1-256351 that such sericin gel, even by merely being left to stand without any further treatment. More specifically, it has been explicitly ascertained by me that JP1-256351 explicitly discloses:

An aqueous fibroin solution and aqueous sericin solution are both gelled even by leaving it as stands [emphasis added]

9. In contrast, the sericin and/or hydrolyzed product used in the present invention cannot be gelled as an aqueous solution in the absence of gelling agent, with the aqueous solution thus being maintained upon standing, unlike the sericin in JP1-256351. Thus the chemical or physical structure of the sericin used in the present invention is different from the sericin used in the applied reference;

10. Accordingly, JP 1-256351 neither discloses nor suggests to me, one skilled in the art, preparation of the inventive composition attaining the advantageous improvements documented in the present application; and

11. All statements made herein of my own knowledge are true and all statements made on information and belief are believed to be true; and further these statements are made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and such willful false statement may jeopardize the validity of the application or any patent issued thereon.

March 23, 2005
Date

Masahiro Sasaki
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